

APPLICANT(S): SALVI, Annibale et al.

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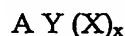
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Page 3

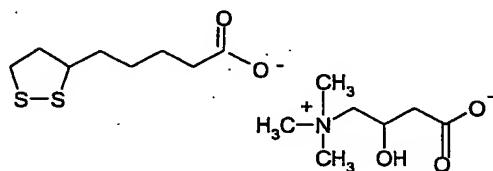
### AMENDMENTS TO THE CLAIMS

#### In the Claims:

1. (Original) Salt of thioctic acid with L-carnitine with the formula:



where A is



where Y is the cation of an alkaline metal, of an alkaline earth metal or is a quaternary ammonium group,

X is A or OH<sup>-</sup>,

x is equal to 0 when Y is the cation of an alkaline metal or a quaternary ammonium group and equal to 1 when Y is an alkaline earth metal.

2. (Original) Salt as claimed in claim 1 wherein Y is chosen from the group consisting of Na<sup>+</sup> and K<sup>+</sup>.

3. (Original) Salt as claimed in claim 1 wherein Y is chosen from the group consisting of Mg<sup>++</sup> and Ca<sup>++</sup>.

4. (Original) Salt as claimed in claim 1 wherein Y is a tetralkyl ammonium wherein the alkyl groups equal or different among each other are linear or branched and have from 1 to 10 carbon atoms.

5. (Original) Salt as claimed in claim 1 wherein the thioctic acid is in raceme form.

6. (Original) Salt as claimed in claim 1 wherein the acid is in optically active form and chosen from -R(+) or S(-) thioctic acid.

7. (Original) Process for the preparation of a salt as claimed in claim 1 comprising the following stages:

- a) preparing a solution of an alkaline, alkaline earth metal or a quaternary ammonium salt of L-carnitine in a linear or branched C<sub>1</sub>-C<sub>5</sub> alcohol, said solution having a L-carnitine concentration between 10% and 30% w/v;

APPLICANT(S): SALVI, Annibale et al.

SERIAL NO.: Not Yet Assigned

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Page 4

- b) adding slowly the solution of stage a) to a solution of thioctic acid, with a concentration between 5% and 15%, in a solvent chosen from the group consisting of ketones with b.p. above 75°C, esters with b.p. above 75°C, acetonitrile and linear or branched alcohols with a number of carbon atoms above 3, and
- c) isolating the salt of formula (I) from the reaction mixture.

8. (Original) Process as claimed in claim 7 wherein in stage a) said alcohol is methanol.

9. (Currently Amended) Process as claimed in claim [[1]] ] 7 wherein in stage b) the solution of L-carnitine is added to the solution of thioctic acid in such a quantity that in the final mixture the molar ratio between the thioctic acid and the L-carnitine is comprised between 0.85 and 1.15.

10. (Currently Amended) Process for the preparation of a salt as claimed in claim 1 comprising the following stages:

- a) preparing a solution of an alkaline, alkaline earth metal or a quaternary ammonium salt of L-carnitine in a linear or branched C<sub>1</sub>-C<sub>5</sub> alcohol, said solution having a L-carnitine concentration between 10% and 30% w/v;
- b) adding slowly the solution of stage a) slowly to a solution of thioctic acid, with a concentration between 5% and 15%, in a solvent chosen from the group consisting of ketones with b.p. above 75°C, esters with b.p. above 75°C, acetonitrile and linear or branched alcohols with a number of carbon atoms above 3, and
- c) isolating the salt of formula (I) from the reaction mixture,  
said stage c) comprising the following operating [[phases]] phases:
  - i) removing partially the solvent in which the L-carnitine was dissolved by distillation under vacuum;
  - ii) adding the same solvent in which the thioctic acid was dissolved;
  - iii) cooling the mixtures to a temperature between 0 and 30°C;
  - iv) separating the precipitate obtained.

11. (Original) Process as claimed in claim 10 wherein in stage ii) the solvent is added in the quantity required to replace the solvent removed in stage i).

12. (Original) Process as claimed in claim 10 wherein the product obtained in stage iv) is washed and dried.

APPLICANT(S): SALVI, Annibale et al.

SERIAL NO.: Not Yet Assigned

FILED: Herewith

Page 5

13. (Original) Pharmaceutical composition comprising the salt as claimed in claim 1 together with suitable excipients and/or diluents.

14. (Original) Dietary supplement comprising the salt as claimed in claim 1 together with suitable excipients and/or diluents.